

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE
COMPANY, JOHN HANCOCK
VARIABLE LIFE INSURANCE
COMPANY and MANULIFE
INSURANCE COMPANY,

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

CIVIL ACTION NO. 05-11150-DPW

**ABBOTT'S DEPOSITION DESIGNATIONS AND COUNTER DESIGNATIONS
FOR JIM LOOMAN**

Defendant Abbott Laboratories ("Abbott") respectfully submits the attached deposition designations and counter-designations for the February 1, 2007 deposition of Jim Looman, M.D., Medical Director, Abbott B.V., Netherlands (ABT-518).

Dated: February 18, 2008

Respectfully submitted,

ABBOTT LABORATORIES

By: /s/ Eric J. Lorenzini
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CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on February 18, 2008.

Date: February 18, 2008.

/s/ Ozge Guzelsu

Jim Looman Deposition Designations

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
2/1/2007	Looman, Jim	10:15-10:24	No Counter				
2/1/2007	Looman, Jim			6:2-9:17			
2/1/2007	Looman, Jim			11:1-14:22			
2/1/2007	Looman, Jim			18:24-20:5			
2/1/2007	Looman, Jim			20:14-21:13			
2/1/2007	Looman, Jim			21:14-22:19			
2/1/2007	Looman, Jim			23:3-23:14			
2/1/2007	Looman, Jim			33:4-34:2			
2/1/2007	Looman, Jim			35:23-37:9			
2/1/2007	Looman, Jim	43:1-43:12	No Counter				
2/1/2007	Looman, Jim	44:13-44:16	43:23-44:12				
2/1/2007	Looman, Jim			44:17-45:6			
2/1/2007	Looman, Jim	50:4-51:9	No Counter		7	BK	
2/1/2007	Looman, Jim	51:18-51:21	51:22-52:9		7	BK	
2/1/2007	Looman, Jim	52:10-52:16	No Counter		8	X	
2/1/2007	Looman, Jim	53:19-54:11	54:12-56:18		8	X	

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
2/1/2007	Looman, Jim	56:23-57:11	No Counter		8	X	
2/1/2007	Looman, Jim	58:6-59:1	No Counter		8	X	
2/1/2007	Looman, Jim			61:4-61:12			
2/1/2007	Looman, Jim	62:7-63:23	63:24-64:9				
2/1/2007	Looman, Jim	64:22-65:10	65:11-65:21				
2/1/2007	Looman, Jim	65:23-66:6	No Counter				
2/1/2007	Looman, Jim	72:19-73:7	No Counter		9	S	
2/1/2007	Looman, Jim	76:2-76:16	No Counter		10	U	
2/1/2007	Looman, Jim	79:12-79:16	79:8-79:11		8	X	
2/1/2007	Looman, Jim	84:22-85:10	84:13-84:21				
2/1/2007	Looman, Jim	84:22-85:10	85:11-85:24		12	V	
2/1/2007	Looman, Jim			95:4-95:16			
2/1/2007	Looman, Jim			97:15-98:2			
2/1/2007	Looman, Jim	102:23-103:11	103:12-104:23		18	AC	
2/1/2007	Looman, Jim			102:5-102:20			
2/1/2007	Looman, Jim			107:4-107:19			
2/1/2007	Looman, Jim	108:13-108:21	108:22-109:4		21	51	
2/1/2007	Looman, Jim			109:22-110:9			

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
2/1/2007	Looman, Jim	110:23-112:2	No Counter		21	51	
2/1/2007	Looman, Jim	113:9-113:14	No Counter		21	51	
2/1/2007	Looman, Jim			113:16-114:7			
2/1/2007	Looman, Jim			124:21-125:10			
2/1/2007	Looman, Jim			125:23-127:20			
2/1/2007	Looman, Jim			129:10-130:8			
2/1/2007	Looman, Jim	136:21-138:11	No Counter		26	BL	
2/1/2007	Looman, Jim			151:14-152:18			

Color Key to Deposition Designations

 **Designation by Plaintiffs**

 **Counter Designation by Defendants**

 **Designation by Defendants**

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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS

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5 JOHN HANCOCK LIFE INSURANCE)
6 COMPANY, JOHN HANCOCK VARIABLE)
7 LIFE INSURANCE COMPANY and)
8 MANULIFE INSURANCE COMPANY)
9 (f/k/a INVESTORS PARTNER)
10 INSURANCE COMPANY),)

11 Plaintiffs,) Civil Action No.

12 -vs-) 05-11150-DPW

13 ABBOTT LABORATORIES,)
14 Defendant.)

15

16

17

18 THE VIDEOTAPED DEPOSITION OF
19 JIM LOOMAN

20

21 February 1, 2007

22

23

24

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1 A. Fair.

2 Q. Dr. Looman, where are you presently
3 employed?

4 A. I'm presently employed at Abbott.

5 Q. How long have you been employed there?

6 A. Since -- let me think. April 1, 2000.

7 Q. 2000?

8 A. Yeah.

9 Q. What's your present job at Abbott?

10 A. I'm medical director for the Dutch
11 affiliate at Abbott.

12 Q. What's the Dutch affiliate's name?

13 A. Abbott B.V., which is same -- I think
14 it's the same as Inc. in the US.

15 Q. How long have you held the position of
16 medical director for the Dutch affiliate?

17 A. Now since one and a half years.

18 Q. So, since 2005?

19 A. Yeah, I think my position started
20 February 1, 2005.

21 Q. What are your responsibilities as
22 medical director?

23 A. Overseeing all of the clinical studies
24 being performed in the Netherlands on behalf of

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1 Abbott.

2 Q. What was your position at Abbott before
3 you were medical director?

4 A. Say again, please.

5 Q. Before you were medical director.

6 A. Yes.

7 Q. Before February 2005.

8 A. Yes.

9 Q. What was your position at Abbott?

10 A. Then I was -- I started in 2000 as an
11 associate medical director for European clinical
12 venture.

13 Q. You held that position from 2000 until
14 February 2005?

15 A. Yes, I did.

16 Q. What were your responsibilities as
17 associate medical director?

18 A. I worked as a medical liaison on behalf
19 of the project teams in Abbott Park in the US for
20 European studies.

21 Q. European clinical studies?

22 A. Yes.

23 Q. In the 2000 to 2005 period while you
24 were associate medical director, did you have

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1 responsibilities other than acting as liaison for
2 the project teams for clinical studies?

3 A. No, I did not have.

4 Q. Before you were employed with Abbott,
5 where were you employed?

6 A. I was employed with Mallinckrodt.

7 Q. Can you spell that for the record.

8 A. M-a-l-l-i-n-c-k-r-o-d-t, Inc. in
9 St. Louis. Based in the Netherlands.

10 Q. You live in the Netherlands now?

11 A. I live in the Netherlands, that is
12 correct.

13 Q. Are you a Dutch national?

14 A. Yes, I am.

15 Q. What did you do at Mallinckrodt?

16 A. I was also involved in helping with
17 clinical research for Mallinckrodt.

18 Q. What years were you employed with them?

19 A. I started in 1988 with Mallinckrodt and
20 I left in November of 1999.

21 Q. You went from there to Abbott?

22 A. Yes, I did.

23 Q. Before Mallinckrodt where were you
24 employed?

PART 2

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1 A. I was a resident surgery in the
2 University of Utrecht in the Netherlands.

3 Q. From what institution and when did you
4 earn your medical degree?

5 A. I was trained in the University of
6 Leidan, L-e-i-d-a-n, in the Netherlands.

7 Q. What year did you earn your MD?

8 A. In 1985.

9 Q. Where did you attend undergraduate
10 studies?

11 A. What do you mean with undergraduate
12 studies?

13 Q. College.

14 A. Oh, in the Netherlands in Dordrecht,
15 D-o-r-d-r-e-c-h-t, the Netherlands.

16 Q. When did you graduate?

17 A. In 1976.

18 Q. How did you prepare for your deposition
19 today?

20 A. I flew over to the US on Monday and I
21 met with the attorney yesterday at Abbott Park.

22 Q. Was anyone else present with you when
23 you met with Mr. Lorenzini?

24 A. I briefly met with Mr. Pete Witty who's

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1 also an attorney at Abbott. But the conversation
2 we had with -- was with Mr. Lorenzini.

3 Q. How long did you meet with him for?

4 A. Around about six to seven hours.

5 Q. Were you shown documents in connection
6 with your preparation yesterday?

7 A. Yes, I was.

8 Q. Did those documents refresh your
9 recollection of certain events with respect to this
10 lawsuit?

11 A. Yes, they did.

12 Q. You are familiar with a compound called
13 ABT-518, correct?

14 A. I am.

15 Q. What was your role with respect to the
16 development of ABT-518?

17 A. As an associate medical director, my
18 responsibility was to act as the medical liaison on
19 behalf of the team at Abbott Park with the two
20 sites that participated in the 518 studies.

21 Q. When did you assume responsibilities as
22 liaison for the clinical trial?

23 A. That must have been when Abbott decided
24 to do two studies in the Netherlands.

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1 Q. Was that 2000?

2 A. I do not remember when exactly I was
3 notified that the study was planned, but it must be
4 I would guess in the beginning of 2000, end of '99.

5 Q. Nobody preceded you in your role as
6 liaison, is that right?

7 A. No, I was the first to do that.

8 Q. How did you perform your duties as
9 liaison? What did you do?

10 A. I was the medical contact with the
11 principal investigators at the site, and I directed
12 questions they had back to the clinical team in
13 Abbott Park.

14 Q. Who were the PIs at the sites?

15 A. There were two sites. One site was in
16 Amsterdam in the National Cancer Institute. The PI
17 there was Professor Schellens, Schellens, S-c-h.
18 and the other site was in Utrecht, department of
19 oncology, headed by Professor Voest.

20 Q. At the time you were acting as liaison
21 were you also acting as liaison with respect to
22 other clinical trials?

23 A. Yes, I was.

24 Q. How many others?

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1 A. One other study for Abbott in Europe
2 with another compound.

3 Q. With the same sites?

4 A. Different sites.

5 Q. Was your time divided roughly equally
6 between the two compounds?

7 A. I would say that 518 was of a lesser
8 magnitude because these were only two sites. So,
9 it's difficult to say.

10 Q. So, you spent more time would you say
11 on -- with respect to the other trial than you did
12 on 518?

13 A. Yes, because that was a larger project,
14 more sites.

15 Q. In the 2000 and 2001 period how often
16 did you visit the sites generally?

17 A. You mean in preparation?

18 Q. Yeah, let's start with before the first
19 patient is dosed. How often did you visit the
20 sites during the planning period?

21 A. I would -- I would say that you -- you
22 visit the sites once to discuss the outline of the
23 protocol to see if there is interest of the sites
24 to participate and then you -- most of the times

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1 you come back a second time to go over questions
2 they may have and when they say, "Okay, we will
3 participate in your study," then other monitoring
4 staff people take over and they do the prep work to
5 start up the study and I come back again at a later
6 stage when the study starts to initiate.

7 Q. Who besides you at Abbott worked on the
8 clinical trial for 518?

9 A. In the Netherlands you mean?

10 Q. In the Netherlands.

11 A. We had one dedicated clinical research
12 associate.

13 Q. Who was that?

14 A. Willy Jansen. She worked with me on --
15 with these two sites.

16 Q. What was her title?

17 A. She was a -- at that time she was a
18 senior CRA, clinical research associate.

19 Q. You said she was dedicated. Did she
20 spend 100 percent of her time on the --

21 A. No, but she was -- she was dedicated
22 to -- to work with me on that study, but she was
23 not full time on the study alone.

24 Q. Who besides Willy Jansen on the

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1 Netherlands side worked on the 518 clinical trial?

2 A. At a later stage when Willy handed over
3 her responsibility, her tasks were taken over by
4 another CRA and her name was Else Meijer.

5 Q. So, at any given time there was only one
6 CRA, is that right?

7 A. Correct, yes.

8 Q. Other than the CRA were any other
9 persons at Abbott in the Netherlands involved in a
10 clinical trial?

11 A. No.

12 Q. Let's talk about persons in Abbott US
13 who were involved in the clinical trial. Okay?
14 Who were they?

15 A. The people that I had most contact with
16 on this project 518 were my supervisor, Azmi
17 Nabulsi, who was the clinical project head.

18 Q. You say he is the clinical project head.
19 What does that mean?

20 A. That he has the responsibility to see
21 that the study is run according to protocol and all
22 other responsibilities that come along with that.

23 Q. He is responsible for more than just the
24 clinical trial, though, correct?

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1 group of persons that were just mentioned that
2 worked together to resolve issues only for the
3 clinical aspect of the study.

4 Q. So, you are unaware of other persons who
5 were involved in other aspects of the
6 development --

7 A. That is --

8 Q. Let me finish my question before you
9 answer because otherwise the reporter will throw
10 eggs at both of us.

11 So, you weren't aware of the persons who
12 were responsible for other aspects of the
13 development of 518?

14 A. That is correct.

15 Q. Did you participate in any meetings in
16 person with Dr. Nabulsi regarding 518 in 2000-2001?

17 MR. LORENZINI: Objection. Just to clarify,
18 do you mean face-to-face meetings?

19 MR. ZWICKER: Yeah, for now.

20 BY MR. ZWICKER:

21 Q. Let me ask you a different question.
22 I'll withdraw that one.

23 A. Yeah.

24 Q. Did you come to the United States in the

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1 2000-2001 time period and meet with Dr. Nabulsi and
2 other persons regarding the development of ABT-518?

3 A. Yes, I did.

4 Q. How many times?

5 A. From what I remember, probably two,
6 three times.

7 Q. Were other persons involved in the
8 development of 518 present during those meetings
9 besides Dr. Nabulsi?

10 A. No, it was only people who were on the
11 clinical side.

12 Q. Diane D'Amico and Todd Janus?

13 A. Correct, yes.

14 Q. In the 2000-2001 time period did you
15 participate in any meetings by phone while you were
16 in the Netherlands and Dr. Nabulsi was in the
17 United States?

18 A. Yes, we -- we did have regular
19 teleconferences within the clinical team to relay
20 information coming from the sites and trying to
21 address those.

22 Q. How often were those teleconferences
23 held?

24 A. It was a long time ago. I would think

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1 probably every two weeks.

2 Q. Who participated in them?

3 A. The clinical team. So, Dr. Janus, Diane

4 D'Amico, Dr. Nabulsi if he was available for the

5 conference call, and then Willy Jansen and myself.

6 Q. Do you know what a portfolio review is

7 at Abbott?

8 A. Yes, I've heard of that.

9 Q. Have you ever attended one?

10 A. No.

11 Q. Were you aware that each month Abbott

12 created monthly highlight reports for ABT-518?

13 A. No, I was not aware.

14 Q. What documents did you see during your

15 time as liaison for the 518 clinical trial?

16 A. Documents that were directly related to

17 the start-up of the two studies in the Netherlands.

18 Q. But not documents that related to the

19 overall development --

20 A. No.

21 Q. -- of the compound?

22 A. I did not.

23 Q. Do you know what the ASCO conference is?

24 A. Yes, I know.

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1 Q. What does ASCO stand for?

2 A. The American Society of Clinical

3 Oncology meeting.

4 Q. Did you attend the ASCO conference?

5 A. I did.

6 Q. In 2001?

7 A. I did.

8 Q. Why?

9 A. Because we use these meetings also to
10 bring together the team, to exchange experiences,
11 have face-to-face meetings and also have an
12 opportunity to talk to investigators that are at
13 that meeting.

14 Q. Dr. Looman, what were the objectives of
15 the clinical trial for ABT-518?

16 For the record the trial was known as
17 M00-235, correct?

18 A. That is correct, yes.

19 Q. I'm just going to refer to it as the
20 clinical trial.

21 A. Okay.

22 Q. Okay? What were the objectives for the
23 clinical trial?

24 A. It was a typical Phase I oncology study,

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1 which was aiming at looking at the toxicity
2 associated with the dosages that were going to be
3 given to patients and looking at the safety profile
4 of the product.

5 In addition, this study also had a -- a
6 subsection in the protocol which was to look at
7 pharmacokinetic parameters.

8 Q. PK is the -- means the rate at which the
9 compound is absorbed in the body. Is that fair?

10 A. That is correct, yes.

11 Q. Dr. Looman, isn't it also true that
12 Abbott viewed the clinical trial as also looking at
13 efficacy for 518?

14 A. No, it was not. The intention -- in
15 Phase I studies, because of the size of the study,
16 it is not possible to look at safety in an
17 objective manner. So, that is not one of the
18 primary objectives of a Phase I study. It was not
19 the case in this study as I remember.

20 MR. LORENZINI: Dr. Looman, you just referred
21 to safety there. The question was about looking at
22 efficacy.

23 THE WITNESS: Yeah.

24 MR. LORENZINI: I just want to make sure.

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1 MR. ZWICKER: I understood his answer.

2 BY MR. ZWICKER:

3 Q. Do you remember persons within Abbott
4 describing the clinical trial as a combination of a
5 Phase I and Phase II clinical trial?

6 A. As far as I was concerned this was a
7 Phase I study, but as the traditional setup of
8 Phase I versus Phase II is that in Phase II you
9 also look at increasing doses to look for toxicity.
10 That part was also included in this Phase I study.

11 So, there was -- it is correct to say
12 that there were, let's say, traditional Phase II
13 elements, which is dose escalation, were built into
14 the Phase I study.

15 Q. What about looking at inhibition, do you
16 remember people within Abbott discussing whether or
17 not the clinical trial would look at inhibition of
18 tumors?

19 A. That is not what I remember.

20 MR. ZWICKER: Let's mark this as Looman
21 Exhibit 1.

22 (WHEREUPON, a certain document was
23 marked Looman Deposition Exhibit
24 No. 1, for identification, as of

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1 the first patient in the 518 clinical trial was
2 dosed. Okay?

3 A. Okay.

4 Q. Can you tell me what steps Abbott took
5 to plan the 518 clinical trial?

6 A. I can only tell you what I know what was
7 done in the Netherlands because that's where my
8 responsibility was, which was when Abbott decided
9 to do two Phase I studies in the Netherlands, I was
10 asked by the 518 team to act as medical liaison and
11 find two sites to be our sites for the Phase I
12 program.

13 Q. How did you go about finding the sites?

14 A. Based on knowledge of key opinion
15 leaders in oncology in the Netherlands, I
16 approached the two sites, Amsterdam and Utrecht,
17 because they were well-known names in the field of
18 oncology in the Netherlands.

19 Q. Who was the person at each site that you
20 approached?

21 A. At the Amsterdam site I contacted
22 Professor Schellens and at the Utrecht site I
23 contacted Professor Voest.

24 Q. And the two sites agreed to act as sites

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1 for the trial?

2 A. They did.

3 Q. Is there a contract or some other

4 understanding between Abbott and the sites with

5 respect to the trial?

6 A. Yes, there is.

7 Q. Can you describe that contract for me?

8 A. It is a contract which lays out the

9 principles by which a protocol is going to be

10 executed, which means that it has to be performed

11 according to the rules and regulations of good

12 clinical practice.

13 It also has specifically the name of the

14 protocol that is going to be executed and it has a

15 section which defines what the sites will get as

16 financial reward for participating in the study.

17 Q. What was the financial reward to the

18 sites for participating in the study?

19 A. That is something I do not know by

20 heart. Normally what the procedure is is that

21 based on the procedures that are outlined in the

22 protocol, the sites are asked to give an estimate

23 what they think in their hospital the cost is for

24 running all of these tests, including the time of

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1 the physician working on the study and the study
2 nurse who participates as well for the data
3 collection, and that gives an aggregate; and then
4 the aggregate is divided by the expected number of
5 patients to give a per patient cost and that is
6 mentioned in the protocol -- in the contract.

7 Q. And Abbott agrees to bear that cost?

8 A. That -- that is being negotiated up
9 front before the start of the study between the
10 site and Abbott; and if there is agreement, then
11 the contract is signed, that is correct.

12 Q. Does Abbott bear that cost if the study
13 is terminated before the first patient is dosed?

14 MR. LORENZINI: Objection; lacks foundation.

15 BY MR. ZWICKER:

16 Q. And I'm talking about this trial.

17 A. The contracts should have a specific
18 section in it that defines what should happen
19 between the two parties when the study should
20 terminate before the first patient is enrolled.

21 Q. Do you remember what provision was made?

22 A. No, I cannot remember that.

23 Q. What persons at each site were involved
24 in the clinical trial?

PART 5

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1 A. Obviously the PI, the principal
2 investigator.

3 Q. That was Schellens and Voest?

4 A. Yes, they are the end responsible people
5 for the study.

6 In the case of Professor Schellens, he
7 was also the physician who was doing the work as
8 laid out in the protocol.

9 In the case of Professor Voest, he had a
10 staff member who he delegated that work to and that
11 was Dr. Zonnenberg.

12 In addition to that, the PK section of
13 the Phase I protocol was delegated to PK people in
14 the respective hospitals. In Amsterdam, that was
15 Professor Beijenen who was the head of pharmacology
16 at that hospital, at the Dutch Cancer Institute,
17 and in Utrecht it was Dr. Beerepoot.

18 Q. And the role as the PK physicians is to
19 monitor the -- how long the compound stays in the
20 body?

21 A. Well, they collect the samples that are
22 needed to do the PK analysis and they run the
23 tests.

24 Q. Other than the PIs and the physicians at

1 the sites and the physicians at the PK sections,
2 who else is involved in the clinical trials in the
3 Netherlands for the -- for the 518 study?

4 A. Traditionally, and that was also the
5 case in this study, each site will have a study
6 nurse who will coordinate, let's say, all of the
7 logistics around the study, so the patients that
8 need to come in for reviews, the availability of
9 material, samples being taken, et cetera.

10 Q. And the contract between Abbott and the
11 sites provides for some kind of compensation for
12 the persons involved at the sites with respect to
13 the studies?

14 A. That is correct.

15 Q. Any other persons besides those you've
16 mentioned involved in the sites?

17 A. I think that there are -- this is
18 complete.

19 Q. On the Abbott side the person that
20 monitors the sites is the CRA?

21 A. That is correct.

22 Q. That was at first Willy Jansen?

23 A. Yes.

24 Q. And then the second person?

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1 Q. Would you agree with me that the
2 planning of the 518 study required a significant
3 amount of time for persons at Abbott?

4 A. Yes, that would be true.

5 Q. And would you agree that it also
6 required a substantial amount of time for persons
7 in the Netherlands?

8 A. Yes, that is also true.

9 Q. Would you also agree that the planning
10 and implementation of the 518 study required a
11 significant financial commitment from Abbott?

12 A. Yes, that would be true.

13 Q. Do you know based on your experience how
14 much money would have been committed by Abbott to
15 the clinical trial before the first patient was
16 dosed?

17 MR. LORENZINI: Objection; lacks foundation.

18 BY THE WITNESS:

19 A. No, I cannot say that because that
20 involves many other areas than clinical and I was
21 not involved with that. So I cannot answer that.

22 BY MR. ZWICKER:

23 Q. Let me ask the question a different way.

24 Focusing just on the clinical trial, do

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1 you know how much money was committed by Abbott for
2 the clinical trial before the time the first
3 patient was dosed?

4 A. No, I do not know.

5 Q. Based on your experience with other
6 trials, do you have an estimate of the percentage
7 of a budget that's spent on a clinical trial before
8 the first patient is dosed?

9 MR. LORENZINI: Objection.

10 BY THE WITNESS:

11 A. No, I do not know.

12 BY MR. ZWICKER:

13 Q. Would you agree that a substantial
14 amount of money is spent by Abbott before the first
15 patient is dosed?

16 A. That would be true.

17 Q. How long did Abbott project the clinical
18 trial to take from dosing to completion?

19 A. That's difficult to say in exact numbers
20 because this was a dose escalating study, looking
21 at a moment of maximum tolerated dose; and one
22 could never upfront predict at what level the study
23 would reach toxicity and thus end. So, that is
24 difficult to say.

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1 Q. But we're talking months or years. Is
2 that fair?

3 A. If -- if you were to take a standard
4 Phase I study, normally a Phase I study would be
5 lasting, I would -- I would say between one and two
6 years.

7 (WHEREUPON, a certain document was
8 marked Looman Deposition Exhibit
9 No. 3, for identification, as of
10 02-01-2007.)

11 MR. ZWICKER: Before the witness is Looman
12 Exhibit 3.

13 BY MR. ZWICKER:

14 Q. Dr. Looman, if you wouldn't mind
15 reviewing the first portion of the document
16 entitled "Clinical," No. 1, and let me know when
17 you are done.

18 A. Okay. I've read it.

19 Q. Dr. Looman, if you wouldn't mind
20 focusing on the first -- the second bullet point
21 under "Clinical." It says, "PK Teleconference on
22 1/29/01 with Schellens lab went well."

23 I apologize for my pronunciation, which
24 I am sure is not right.

PART 6

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1 meeting.

2 Same answer, you didn't attend?

3 A. That is correct. I did not attend.

4 Q. Do you recall in March of 2001 receiving
5 an e-mail from Dr. Nabulsi informing you that all
6 development activities for ABT-518 had been
7 terminated?

8 MR. LORENZINI: Objection. You can answer.

9 BY THE WITNESS:

10 A. I do not remember a memo which specifies
11 what you just said. I do remember that I received
12 a memo from the clinical team, and I cannot
13 remember if that was from Dr. Nabulsi or somebody
14 else from the clinical team, to inform me that the
15 studies needed to be stopped.

16 (WHEREUPON, a certain document was
17 marked Looman Deposition Exhibit
18 No. 7, for identification, as of
19 02-01-2007.)

20 MR. ZWICKER: The record should reflect that
21 before the witness is Looman Exhibit No. 7, which
22 is an undated typewritten note to Jim from Azmi.

23 BY MR. ZWICKER:

24 Q. Dr. Looman, if you wouldn't mind, could

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1 you review Exhibit No. 7 and tell me if you recall
2 receiving it.

3 A. I do recall receiving it.

4 Q. How did you receive it? By what method?

5 Was it an e-mail?

6 A. If my memory serves me correct, this was
7 indeed an e-mail.

8 Q. From Dr. Nabulsi?

9 A. Yes.

10 Q. Do you remember receiving it on a Friday
11 evening?

12 A. I cannot say that. I cannot -- I cannot
13 remember that it was a Friday evening.

14 Q. Do you remember receiving it at night?

15 A. I cannot remember that.

16 Q. Were you surprised to get it?

17 A. Yes, I was.

18 Q. Before you received this e-mail from
19 Dr. Nabulsi, did you have any indication that
20 development activities for 518 would be terminated?

21 A. No, I did not.

22 Q. Following your receipt of the e-mail
23 from Dr. Nabulsi, did there come a time when you
24 had a telephone conversation with him?

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1 A. It -- he called me. It wasn't a
2 teleconference. It was just a person-to-person
3 call. I remember that was late in the day, during
4 that weekend, where he informed me of this news and
5 that he asked me to act on it.

6 Q. So, you do remember having a telephone
7 conversation with Dr. Nabulsi regarding the subject
8 of this e-mail over the course of a weekend?

9 A. That is correct.

10 (WHEREUPON, a certain document was
11 marked Looman Deposition Exhibit
12 No. 8, for identification, as of
13 02-01-2007.)

14 MR. ZWICKER: Before the witness is Looman
15 Exhibit No. 8, which is an e-mail from Diane
16 D'Amico to Azmi Nabulsi and others.

17 BY MR. ZWICKER:

18 Q. Dr. Looman, if you wouldn't mind looking
19 at the entry for Sunday, March 11, and reviewing it
20 to yourself.

21 A. Yes, I've read that.

22 Q. It says that "Dr. Nabulsi phoned Jim
23 Looman (Associate Director, EVR Netherlands) to
24 tell him that the M00-235 study should be put on

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1 hold. Jim Looman was instructed to contact both
2 Dr. Schellens and Dr. Zonnenberg to notify them of
3 the hold."

4 And the time is 10:00 a.m. CST and 1700

5 CET. Do you see that?

6 A. Yes, I see that.

7 Q. Is CET Netherlands time?

8 A. Central European Time, which is the zone

9 in which the Netherlands is in.

10 Q. So that is 5:00 p.m.?

11 A. That is 5:00 p.m.

12 Q. On a Sunday?

13 A. On a Sunday.

14 Q. And do you recall that that's the time

15 that you and Dr. Nabulsi spoke?

16 A. That's correct.

17 Q. Let's go back to Exhibit No. 7.

18 A. Yes.

19 Q. The first line of the e-mail says, "Jim,

20 Greetings. We had a project review with upper

21 management this Wednesday. During this review

22 there was a concern regarding the continuation with

23 ABT-518 development."

24 Do you see that?

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1 A. Yes.

2 Q. Did you and Dr. Nabulsi during your

3 telephone call discuss the project review meeting

4 with upper management?

5 A. In that telephone conference he informed

6 me of the outcome of the meeting.

7 Q. Did he tell you who said what at the

8 meeting?

9 A. He told me that he and Dr. Nisen were

10 informed by senior management that the study was

11 going to put on hold.

12 Q. I'm asking about the very first sentence

13 there.

14 A. Yes.

15 Q. Where there is a reference to management

16 meeting. The e-mail says, "During this review,

17 there was a concern regarding the continuation with

18 ABT-518 development."

19 Did Dr. Nabulsi tell you what concerns

20 had been expressed regarding the continuation of

21 ABT-518 development at the management meeting?

22 A. No, he just informed me that the outcome

23 was that we had to stop the study.

24 Q. Do you recall any discussion during the

PART 7

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1 telephone conversation with Dr. Nabulsi about
2 Abbott's competitors with MMPI compounds under
3 development? Talking about this telephone
4 conversation now.

5 A. Let me think. No. The conversation as
6 far as I can remember dealt with the Dutch studies
7 and that this decision impacted only Dutch studies
8 without any information about competitors.

9 Q. The next line reads, "Although we
10 thought we would be able to continue at this time,
11 I and Perry have learned, 45 minutes ago, that we
12 should stop all development activities
13 immediately."

14 Do you see that?

15 A. Yes.

16 Q. What did Dr. Nabulsi tell you about the
17 reasons why all development activities should be
18 stopped immediately?

19 A. The conclusion of the review by that
20 upper management meeting was that the study could
21 not continue. That was what he told me.

22 Q. By upper management --

23 A. Yes.

24 Q. -- did Dr. Nabulsi identify Dr. Leiden?

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1 A. He didn't mention a name, no.

2 Q. The e-mail he wrote you says, "We should
3 stop all development activities immediately."

4 Do you see that?

5 A. Yes.

6 Q. Did he reiterate to you during your
7 phone conversation with him on March 11 that all
8 development activities for ABT-518 would stop?

9 A. As far as -- as far as I can remember we
10 only discussed the clinical aspect of the project
11 where I was involved with but no other aspects.
12 Those were not discussed in that conference call.

13 Q. Did you ask him whether activities other
14 than clinical trial would stop?

15 A. No, I did not.

16 Q. Were you interested?

17 A. Actually I was more interested in the
18 clinical studies.

19 Q. Did you view the clinical study as the
20 most important aspect of 518's clinical
21 development?

22 Sorry. Let me strike that.

23 Did you view the trial as the most
24 important aspect of 518's development as of

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1 March the 11th?

2 A. From a medical perspective being a

3 doctor, I -- I would say that initiatives that

4 involve cancer patients for me are regarded a very

5 high priority, yes.

6 Q. And in terms of all the other

7 development activities for 518, did you view the

8 clinical trial as the most important?

9 MR. LORENZINI: Objection.

10 BY THE WITNESS:

11 A. From my medical background, yes.

12 BY MR. ZWICKER:

13 Q. Is it your testimony that you don't

14 recall discussing the reasons for the termination

15 of development activities with Dr. Nabulsi on

16 March 11?

17 A. No, that is not true. Because I wanted

18 to receive from him information that I could relay

19 to the principal investigators why the study had

20 stopped by this decision. So, I asked him.

21 Q. You asked him what the reasons were for

22 why development activity should stop?

23 A. That is correct.

24 Q. What did he tell you?

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1 A. Then he referred to the fact that in
2 that meeting, that upper management meeting, a
3 portfolio analysis had been conducted and the
4 result of that portfolio analysis was that the
5 study 235 would not be continued.

6 Q. Did he tell you what the reasoning was
7 for the portfolio analysis in discontinuing the
8 clinical trial?

9 A. What I remember was that when this
10 happened, this was very shortly after Abbott had
11 acquired Knoll, another company, pharmaceutical
12 section of BASF in Germany, which implicated that
13 we received a lot of new products and projects in
14 our pipeline as a result of that acquisition and
15 that one of the reasons of this review was to
16 prioritize which of the projects had the highest
17 priority for development.

18 Q. Did Dr. Nabulsi tell you that ABT-518
19 did not have a high priority for development?

20 A. Not high enough to continue.

21 Q. Did he tell you why that was?

22 A. No, I cannot -- I cannot remember. The
23 decision was that 518 was not high enough on the
24 priority list to continue and that was the reason

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1 for discontinuation.

2 Q. He relayed that to you during your phone

3 conversation?

4 A. Yes, that is correct.

5 Q. Did he tell you that that decision had

6 been made by Dr. Leiden?

7 A. I cannot remember that the name Leiden

8 was mentioned in that conversation.

9 Q. You knew who Dr. Leiden was on March 11,

10 right?

11 A. I know who Dr. Leiden was, yes.

12 Q. What was his title?

13 A. I think he was the vice president GPRD.

14 Q. Global pharmaceutical research and

15 development?

16 A. That is correct.

17 Q. Did you understand at the time that

18 Dr. Leiden had the authority to terminate

19 development of compounds?

20 A. Yes, I knew that Dr. Leiden in the

21 hierarchy of Abbott's clinical research was the

22 highest ranking officer. So, that would mean that

23 he would have that authority.

24 Q. Before March 11 had you ever spoken with

PART 8

1 Q. How many patients were enrolled as of
2 March 11?

3 A. None.

4 Q. You said that patients were going to be
5 dosed on March 12?

6 A. Yes, that is correct.

7 Q. How many?

8 A. One -- one was planned to be dosed in
9 Utrecht on the Monday morning and a second patient
10 was planned, but I cannot remember if it was -- if
11 he was planned to be dosed on the same Monday. But
12 one was certainly planned to be dosed.

13 Q. In your experience at Abbott had you
14 ever been involved in a situation where a clinical
15 trial had been terminated before the first patient
16 was dosed?

17 A. No. This was my first experience with
18 this situation.

19 Q. In your entire career have you ever been
20 involved in a situation where a clinical trial was
21 terminated before the first patient was dosed?

22 A. No. This was the first time.

23 Q. As a result of your conversation with
24 Dr. Nabulsi on March the 11th, what were you asked

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1 to do?

2 A. To as soon as reasonably possible try to
3 contact the sites and specifically the PIs to
4 notify them of Abbott's decision to not continue
5 and to ask them to refrain from enrolling patients,
6 dosing patients.

7 Q. In your mind on March 11, was Abbott's
8 decision to terminate the clinical trial a final
9 decision?

10 A. I --

11 MR. LORENZINI: Objection; calls for
12 speculation.

13 BY THE WITNESS:

14 A. At that moment my information was that
15 the stop was going to be a permanent one.

16 BY MR. ZWICKER:

17 Q. And that was information you got from
18 Dr. Nabulsi?

19 MR. LORENZINI: Objection.

20 BY THE WITNESS:

21 A. In the teleconference we had together,
22 there was no information relayed to me that
23 indicated differently.

24 BY MR. ZWICKER:

1 Q. Dr. Looman, in your mind on March 11, is
2 it fair to say that you viewed the termination of
3 the clinical trial as a substantial negative event
4 that made the successful development of 518
5 unlikely?

6 MR. LORENZINI: Objection.

7 Could you read back the question,
8 please.

9 (WHEREUPON, the record was read
10 by the reporter as requested as
11 follows: Q. Dr. Looman, in your
12 mind on March 11, is it fair to say
13 that you viewed the termination of
14 the clinical trial as a substantial
15 negative event that made the
16 successful development of 518
17 unlikely?)

18 MR. LORENZINI: Objection. But you can
19 answer.

20 BY THE WITNESS:

21 A. Yes, that would be true because this was
22 the first Phase I study with 518, and stopping it
23 prematurely would not benefit the project.

24 BY MR. ZWICKER:

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1 Q. So, you believe that the development of
2 518 was effectively terminated on March 11. True?

3 MR. LORENZINI: Objection; calls for
4 speculation.

5 BY THE WITNESS:

6 A. No, I cannot say that. I can say that
7 the clinical part of the development was stopped,
8 but I did not have any information about other
9 aspects of the project.

10 BY MR. ZWICKER:

11 Q. You would agree with me that without a
12 successful Phase I clinical trial, development of
13 518 couldn't proceed, right?

14 A. It would -- it is not -- you cannot say
15 that the project cannot continue, but you can never
16 bring a product to market without a successful
17 Phase I study.

18 Q. And as of March 11, the only Phase I
19 clinical trial for 518 was the Netherlands study,
20 correct?

21 A. That is correct.

22 Q. In your mind on March 11, did you
23 believe that shutting down the clinical trial would
24 negatively impact Abbott's reputation with the

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1 sites?

2 A. Yes, I did.

3 Q. Why?

4 A. Because Abbott was in the process of
5 developing oncology products. We didn't at that
6 time have any oncology product on the market from
7 which -- coming from the oncology group. So, the
8 oncology group was building relationships with
9 oncologists for further development of their group
10 of products of which 518 was one.

11 And I was afraid that discontinuation of
12 this study would be regarded negatively by the
13 investigators and, as such, negative on Abbott's
14 image as an oncology company.

15 Q. And potentially impede Abbott's efforts
16 to develop oncology drugs in the Netherlands?

17 MR. LORENZINI: Objection.

18 BY THE WITNESS:

19 A. I -- I couldn't say that. But it would
20 mean that we would have to reestablish a level of
21 confidence with those investigators again.

22 BY MR. ZWICKER:

23 Q. So, in your mind terminating this
24 clinical trial negatively impacted Abbott's

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1 relationships with clinical sites in the
2 Netherlands?

3 A. With those two specific sites.

4 Q. Did you view those two specific sites as
5 important sites?

6 A. Yes.

7 Q. Have you told me everything you can
8 remember about your conversation with Dr. Nabulsi
9 on March 11, 2001?

10 A. One thing that I did express during that
11 conference call that I haven't mentioned is that
12 this all -- this took place Sunday evening at
13 5 o'clock and the patient was going to be dosed the
14 next morning in Utrecht.

15 So, I felt that we had very little time
16 to do all of the necessary -- necessary activities
17 to discontinue this study.

18 Q. What activities were necessary to
19 discontinue the study?

20 A. Well, first and foremost, to inform the
21 involved people at the sites.

22 Q. What else?

23 A. I think --

24 MR. LORENZINI: Are you asking now about what

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1 that occasion. I'm -- as I told you earlier, my
2 information from Dr. Nabulsi was that the study was
3 going to be stopped, and I probably used those
4 words.

5 Q. And you didn't give them any indication
6 that the study would be restarted, did you?

7 A. No.

8 Q. Do you recall anything else about your
9 conversations with Dr. Voest or Jolanda Maaskant on
10 March the 12th?

11 A. No, this is what we discussed.

12 Q. You asked to speak with Dr. Schellens,
13 correct?

14 A. Correct.

15 Q. He wasn't available?

16 A. No, he wasn't available.

17 Q. Did you ask that he call you back?

18 A. Yes, I did.

19 (WHEREUPON, a certain document was

20 marked Looman Deposition Exhibit

21 No. 9, for identification, as of

22 02-01-2007.)

23 MR. ZWICKER: Before the witness is Looman

24 Exhibit No. 9, which is an e-mail from Diane

1 D'Amico to James Looman and others.

2 BY MR. ZWICKER:

3 Q. Dr. Looman, do you recognize this

4 exhibit?

5 A. Yes, I do.

6 Q. Do you remember receiving it?

7 A. Yes, I do.

8 Q. Do you know why Diane D'Amico was

9 instructed to contact Professor Schellens?

10 A. No, I do not know.

11 Q. Did you have any discussions with

12 Dr. Nabulsi about what role Diane D'Amico would

13 play in shutting down the trial?

14 A. No.

15 Q. The e-mail is addressed to a series of

16 persons, one of which is Paige Gjelsten?

17 A. Um-hmm.

18 Q. Who was she? What was her role with

19 respect to the trial?

20 A. Paige Gjelsten was the clinical research

21 associate in Abbott US. So, the equivalent of

22 Willy Jansen in the Netherlands.

23 Q. Who was Lori Rountree?

24 A. Lori Rountree was the director of

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1 remember that I did.

2 (WHEREUPON, a certain document was

3 marked Looman Deposition Exhibit

4 No. 10, for identification, as of

5 02-01-2007.)

6 MR. ZWICKER: Before the witness is Looman

7 Exhibit No. 10, which is an e-mail from Jim Looman

8 to Azmi Nabulsi and others.

9 BY MR. ZWICKER:

10 Q. Dr. Looman, do you recognize

11 Exhibit No. 10?

12 A. I do.

13 Q. It refers to a conversation that you had

14 with the study coordinator of 518 at Professor

15 Schellens' site. Do you see that?

16 A. Yes.

17 Q. Who did you speak with?

18 A. That was the study coordinator at

19 Professor Schellens' site. So another person than

20 Jolanda Maaskant. But I cannot remember her name

21 anymore.

22 Q. So, this is a second conversation?

23 A. A second conversation, yeah.

24 Q. What do you remember -- do you remember

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1 had been terminated?

2 A. No, I do not know.

3 Q. If you go back to Exhibit No. 8.

4 A. Yes.

5 Q. And look at the portion that reflects
6 your conversation with Jolanda Maaskant.

7 A. Yes.

8 Q. Do you see a reference there to "The
9 site sent home a patient who was waiting to
10 enroll"? Very last sentence.

11 A. Yes, I see that.

12 Q. Is it fair, then, that one of the things
13 that occurred as a result of the instruction to
14 halt the trial was that the Amsterdam site sent
15 home a patient?

16 A. Yes.

17 Q. Did the sites take any action with
18 respect to the PK process in response to the
19 direction to shut down the trial?

20 A. In the case of Amsterdam, since there
21 was no patient, there were no -- there was no
22 material. So there was no action.

23 In the case of Utrecht, as part of the
24 enrollment of the first patient, the activities to

PART 10

1 degradation or things like that.

2 So, there were two elements to that

3 separate section of the protocol that were studied

4 at the same time.

5 Q. Do you have any knowledge whether any PD

6 analysis was done with respect to the one patient

7 at the site who was dosed?

8 A. I would be surprised because PD analysis

9 are conducted over longer period of time to see how

10 the body reacts; and since there was only one

11 patient at that time one day in the study, that was

12 too short.

13 Q. Do you remember learning that the halt

14 of the clinical trial was lifted?

15 A. Yes.

16 Q. Who told you?

17 A. I remember receiving an e-mail with that

18 news on Tuesday.

19 Q. From whom?

20 A. If I remember correctly, it was either

21 Diane D'Amico or Paige Gjelsten, one of the two.

22 (WHEREUPON, a certain document was

23 marked Looman Deposition Exhibit

24 No. 12, for identification, as of

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1 02-01-2007.)

2 MR. ZWICKER: Before the witness is Looman

3 Exhibit No. 12, which is an e-mail from Paige

4 Gjelsten to Jim Looman and others dated March 13,

5 2001.

6 BY MR. ZWICKER:

7 Q. Dr. Looman, was this the e-mail you

8 received?

9 A. This is the e-mail I was referring to,

10 that is correct.

11 Q. Was this the first news you had that the

12 hold had been lifted?

13 A. As far as I can remember, yes. As you

14 can see from the date stamp, time stamp it was

15 10:30 in the afternoon -- sorry -- 9:30 in the

16 evening. So, it could well be that I have picked

17 that e-mail up early next morning.

18 Q. The 14th?

19 A. Yeah.

20 Q. When you picked up the e-mail, what did

21 you do?

22 A. What I can remember is that I tried to

23 contact the clinical team to ask them what steps

24 needed to be taken to lift the hold.

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1 So, he was disappointed about the whole
2 thing that was happening with the 518 study, but
3 wanted to continue working with Abbott.

4 Q. Did either of the sites express concern
5 that the halt would result in delays in conducting
6 the trial?

7 A. Not at that moment.

8 Q. Subsequently?

9 A. Not that I remember.

10 Q. Did either of the sites talk about
11 difficulties in restarting the trial, practical
12 difficulties?

13 A. That was not discussed.

14 Q. Did either of the sites talk to you
15 about any financial consequences of the halt?

16 A. Not that I remember.

17 Q. And your testimony was that you don't
18 remember what reasons you provided the sites for
19 why the halt was lifted, is that right?

20 A. That's correct.

21 MR. ZWICKER: Can we mark these three.

22 (WHEREUPON, certain documents were

23 marked Looman Deposition Exhibit

24 Nos. 14, 15 and 16, for

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1 Q. Were you consulted with respect to the
2 letters which are marked as Exhibits 14 through 16?

3 A. Not that I can remember, no.

4 Q. Dr. Looman, isn't it true that
5 notwithstanding the lift on the trial, the
6 studies -- the sites refused to recommence their
7 activities in the days and weeks following
8 March 14?

9 MR. LORENZINI: Objection. Could you read the
10 question back, please.

11 MR. ZWICKER: I'm going to restate it.

12 MR. LORENZINI: I think you misspoke.

13 MR. ZWICKER: I'm going to restate it.

14 BY MR. ZWICKER:

15 Q. Dr. Looman, isn't it true that the sites
16 refused to recommence activities relating to the
17 clinical trial in the days and weeks after
18 March 14?

19 MR. LORENZINI: Objection.

20 BY THE WITNESS:

21 A. As far as I can remember, not all
22 activities were halted. There were some activities
23 that went on because the study was officially
24 restarted by Abbott.

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1 What I do remember was that the sites
2 were going on with activities to plan new patients.

3 Q. Do you remember sending an e-mail to
4 Diane D'Amico that -- telling her that the sites
5 remained dormant following the restart pending
6 further discussions with Dr. Nabulsi?

7 A. That is -- that -- I do remember that.

8 Q. What did you mean when you -- well,
9 let's mark the next exhibit.

10 (WHEREUPON, a certain document was
11 marked Looman Deposition Exhibit
12 No. 17, for identification, as of
13 02-01-2007.)

14 MR. ZWICKER: The record should reflect that
15 before the witness is Looman Exhibit No. 17, which
16 is a series of e-mails dated March 19, 2001 and one
17 e-mail from March 16.

18 BY MR. ZWICKER:

19 Q. Dr. Looman, if you wouldn't mind reading
20 just the e-mails on the first page of the document.

21 A. I've read them.

22 Q. Let's start with the bottom e-mail,
23 which is an e-mail from you to Diane D'Amico and
24 others, where you say, "In the meantime Else and

PART 11

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1 the clinical team that the meetings went well with
2 the two investigators.

3 Q. Clinical teams in the US?

4 A. Yes.

5 Q. And as a result of those meetings, the
6 sites were prepared to restart activities?

7 MR. LORENZINI: Objection; mischaracterizes.

8 BY THE WITNESS:

9 A. What I remember was that the sites,
10 after the hold had been lifted, started to restart
11 activities. The only thing that the PIs wanted to
12 have was this feeling of comfort after talking to
13 Dr. Nabulsi before enrolling any new patients.

14 BY MR. ZWICKER:

15 Q. So, they had restarted activities but
16 had not enrolled new patients?

17 A. That is correct.

18 Q. And once they had met with Dr. Nabulsi
19 they agreed to enroll new patients?

20 A. That is correct.

21 MR. ZWICKER: Let's mark this as the next
22 exhibit.

23 (WHEREUPON, a certain document was

24 marked Looman Deposition Exhibit

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 No. 18, for identification, as of

2 02-01-2007.)

3 MR. ZWICKER: Exhibit 18 is a series of

4 e-mails from Diane D'Amico and Jim Looman dated

5 March 21, 2001.

6 BY MR. ZWICKER:

7 Q. Dr. Looman, do you recognize Exhibit 18?

8 A. I do.

9 Q. Can you review it and let me know when

10 you're done.

11 A. I've read it.

12 Q. You say in the second paragraph, "I have

13 asked Else and Willy to kindly request if there are

14 things that we could do in parallel in the

15 meantime, but I would like to ask all of the team

16 not to start pushing now before we have officially

17 resolved the hold situation. This applies to e.g.

18 requests for getting documents, enrollment

19 planning, et cetera."

20 Dr. Looman, is it fair to say that as a

21 result of the halt on the clinical trial there were

22 delays in getting documents and in planning for the

23 enrollment of patients?

24 A. No, I could not confirm that.

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 Q. What do you mean when you say "This
2 applies to requests for getting documents,
3 enrollment planning, et cetera"?

4 A. The information I received from the
5 sites was that study activities other than
6 enrolling new patients were continuing as per lift
7 of the hold. So, these were logistical activities
8 that were needed to plan new patients, make sure
9 that every aspect of the study was correct in order
10 to be able to enroll patients.

11 Q. What activities were proceeding when the
12 hold was lifted?

13 A. The follow-up of the patient who was
14 enrolled in the study, of course, who continued
15 and, secondly, activities in preparation of
16 enrolling new patients.

17 Q. What activities were those?

18 A. Making sure that the documents were
19 available for patients to sign informed consent, to
20 give the patients the information in writing, make
21 sure that the drug was available, make sure that
22 the case record forms were ready to be used, things
23 like that.

24 Q. How soon after March 21, 2001, did

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 to make a decision about whether to terminate
2 development of ABT-518 based upon competitor data?

3 A. No, I was not.

4 Q. I believe you testified earlier this
5 morning that you attended the 2001 ASCO conference?

6 A. That is correct.

7 Q. Who else attended the ASCO conference in
8 addition to yourself from Abbott?

9 MR. LORENZINI: Objection.

10 BY MR. ZWICKER:

11 Q. Did you attend by yourself?

12 A. There were members of the oncology team
13 present as well.

14 Q. Who were they?

15 A. People that I can remember were
16 Dr. Janus, Dr. Nabulsi, Dr. Humerickhouse.

17 Q. Can you spell that for the record.

18 A. And I believe Diane D'Amico was also
19 there.

20 Q. Did you attend the presentations?

21 A. Some.

22 Q. Do you have an understanding now -- I'll
23 represent to you that the ASCO conference was
24 May 12 to 15, 2001.

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 A. Um-hmm.

2 Q. Did you have an understanding at that
3 time that the future development of 518 was
4 dependent upon receiving positive data regarding
5 Pfizer's MMPI drug known as prinomastat?

6 A. I was not aware of that.

7 Q. Going into the ASCO conference, did you
8 have any understanding that the results of that
9 conference would have any impact on Abbott's
10 decision whether or not to continue with
11 development of 518?

12 A. I was not aware at that time.

13 MR. ZWICKER: Can we mark this as the next
14 exhibit, please.

15 (WHEREUPON, a certain document was
16 marked Looman Deposition Exhibit
17 No. 21, for identification, as of
18 02-01-2007.)

19 MR. ZWICKER: Before the witness is
20 Exhibit 21, which are a series of slides. The
21 first slide is entitled "ASCO 2001 MMPI Update."

22 BY MR. ZWICKER:

23 Q. Dr. Looman, review, if you would,
24 Exhibit 21 and let me know when you're done.

PART 12

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 A. I've read it.

2 Q. Other than sitting here today have you
3 seen this document before?

4 A. No.

5 Q. Were you aware that Abbott was preparing
6 a summary of data at the 2001 ASCO conference in
7 May of 2001?

8 A. Not specifically. It is -- it is
9 routine that some people in the group will make
10 a -- sort of a summary of the highlights of each
11 meeting and then that gets circled back to the
12 persons that have requested that.

13 Q. You had no role in the creation of any
14 summary type documents --

15 A. No, I was not involved in that.

16 Q. Okay. I'm just going to finish the
17 question.

18 You had no role in the preparation of
19 summary details for the 2001 ASCO conference,
20 correct?

21 A. That is correct.

22 Q. As a result of your attendance at the
23 2001 ASCO conference, did you draw any conclusions
24 one way or another whether the data presented was

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 positive or negative for the development of

2 ABT-518?

3 A. We -- I do remember that with the

4 members that I mentioned to you that were present

5 that I remember were present during the ASCO

6 meeting, we did have informal talks about what

7 people's impressions were of these presentations.

8 And I do remember that the news of agents in the

9 MMPI group were not favorable.

10 Q. Who had these conversations?

11 A. I -- I do not know exactly when and

12 where with whom people. These were meetings that

13 we have, for instance, during dinners after the

14 meeting and evenings with the teams. But people

15 that were mentioned were mostly present with that.

16 Q. Did you form your own conclusions

17 regarding whether or not the data was favorable or

18 unfavorable?

19 A. I did not hear back from my team members

20 in the US that as a result of the information from

21 the competitors that our own compound was at risk

22 in any way.

23 Q. So, you didn't hear from your colleagues

24 in the US that the results at ASCO should be

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 construed to -- strike that.

2 You didn't understand from your

3 competitors, your colleagues in the US that the

4 ASCO data was bad for 518?

5 A. No.

6 MR. LORENZINI: Objection; vague as to time.

7 BY THE WITNESS:

8 A. No, that is not what I interpreted.

9 BY MR. ZWICKER:

10 Q. Was your understanding that the ASCO

11 data was neutral for 518 in 2001?

12 MR. LORENZINI: Objection.

13 BY THE WITNESS:

14 A. I cannot answer the question. I -- what

15 I can say is that the discussions that we had, one

16 of the questions -- main questions that were -- was

17 posed in our group of clinical people was whether

18 or not the results from the other compounds was

19 going to be a class effect and if such -- if 518

20 would be impacted by that.

21 As we were at the very early stage in

22 our studies, it was too early to draw any

23 conclusions at that time for 518.

24 BY MR. ZWICKER:

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 Q. From the ASCO data?

2 A. Yes.

3 Q. I'm going to read you a question and
4 answer from the deposition of Azmi Nabulsi that was
5 taken in this case.

6 A. Okay.

7 Q. Okay.

8 "Q. Would you agree with me
9 that the results at ASCO were not
10 conclusive in your mind regarding
11 whether development of ABT-518
12 should continue or stop?

13 "A. In my mind ASCO results
14 were not definitive either way. It
15 did not bring significantly new
16 information as far as I was
17 concerned at the time."

18 Do you agree with Dr. Nabulsi?

19 MR. LORENZINI: Objection; compound, vague and
20 ambiguous.

21 BY THE WITNESS:

22 A. I would like to repeat what I just said
23 is that knowing the data from our own experience
24 with 518, which was just so limited and so short,

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 only in a Phase I study, for me it was impossible
2 to extrapolate to the data that were presented at
3 ASCO from the other compounds.

4 So, certainly there was a question
5 whether or not there would be a relationship, but
6 it couldn't be answered because we were too soon in
7 our development.

8 BY MR. ZWICKER:

9 Q. So, in your own mind the ASCO results
10 were not definitive?

11 A. No --

12 MR. LORENZINI: Objection.

13 BY THE WITNESS:

14 A. Were not definitive.

15 BY MR. ZWICKER:

16 Q. Prior to the ASCO conference in 2001
17 were you personally tracking the development of
18 Abbott's MMPI's competitors?

19 A. No, I was not.

20 Q. So you didn't have information, you
21 personally, about what information Abbott had about
22 its competitors going into the ASCO conference.
23 True?

24 A. That's true. I did not have that

PART 13

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 information.

2 Q. So, you wouldn't know whether

3 information presented at ASCO was information

4 already known to Abbott or new information,

5 correct?

6 A. That -- I would not know that. I didn't

7 know that at that time.

8 MR. ZWICKER: Let's mark this as the next

9 exhibit.

10 (WHEREUPON, a certain document was

11 marked Looman Deposition Exhibit

12 No. 22, for identification, as of

13 02-01-2007.)

14 MR. ZWICKER: Before the witness are a series

15 of documents produced by Abbott in this matter

16 bearing Bates Nos. 556321 through -- well, strike

17 that.

18 There are a series of documents produced

19 by Abbott in this matter that bear different --

20 different Bates numbers.

21 BY MR. ZWICKER:

22 Q. Dr. Looman, if you wouldn't mind turning

23 to the portion of the document that begins with

24 some handwritten notes.

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 Q. Is the meeting that you testified to
2 earlier the meeting that's discussed in this
3 e-mail?

4 A. That is correct.

5 Q. So, following that -- those meetings,
6 the sites began to reenroll patients?

7 A. New patient, yes.

8 Q. So, the shutdown of the clinical trial
9 resulted in at least a two-week delay in
10 enrollment, is that fair?

11 MR. LORENZINI: Objection.

12 BY THE WITNESS:

13 A. No new patients were enrolled before
14 this conversation took place between the PIs and
15 Azmi, Dr. Nabulsi. So, in that period of time no
16 new patients were entered.

17 BY MR. ZWICKER:

18 Q. And the period of time was from the halt
19 of the study until at least March 26, correct?

20 A. That's correct.

21 Q. Did there come a time when you learned
22 that development of 518 had been again terminated?

23 MR. LORENZINI: Objection to characterization.

24 You can answer.

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 THE WITNESS: Okay.

2 BY THE WITNESS:

3 A. What I remember was that I was informed
4 that the study was discontinued for the second
5 time, that is correct.

6 BY MR. ZWICKER:

7 Q. When did you learn that?

8 A. I do not know by heart the date, but
9 what I know was it was sometime after the ASCO
10 meeting.

11 (WHEREUPON, a certain document was
12 marked Looman Deposition Exhibit
13 No. 24, for identification, as of
14 02-01-2007.)

15 MR. ZWICKER: Before the witness is Looman
16 Exhibit No. 24, which is an oncology status report
17 for June the 4th, 2001.

18 BY MR. ZWICKER:

19 Q. Dr. Looman, look at the last page of the
20 document, Section 7 entitled "Issues," and read it
21 for yourself and let me know when you're done.

22 A. I've read it.

23 Q. Does reviewing that paragraph help you
24 recall when you learned that the 518 compound was

1 A. What I remember, which was confirming
2 the discussions, the informal discussions we had at
3 ASCO, was that clinical data from later phase
4 studies with competitor agents did not result in
5 satisfactory efficacy results.

6 Q. From later phase -- later phase studies
7 you mean Phase III studies?

8 A. Yeah, or Phase II or Phase III. Later
9 than our studies, which were in Phase I.

10 Q. And, again, sitting here today you don't
11 know whether Abbott was aware of the results of
12 those Phase II and Phase III studies before ASCO,
13 correct?

14 A. Well --

15 MR. LORENZINI: Objection.

16 BY THE WITNESS:

17 A. -- I was not aware.

18 BY MR. ZWICKER:

19 Q. You weren't aware?

20 A. Yes.

21 Q. You said the reasons for the second
22 discontinuance were different than the reasons you
23 were provided for the first. What did you mean by
24 that?

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 Q. You don't remember whether the specific
2 data relied upon by Abbott was data from the Pfizer
3 drug, prinomastat?

4 A. No, I do not know that.

5 Q. Do you remember whether the data relied
6 on was from a drug called marimastat from British
7 Biotech?

8 A. I do not know if -- if that was part of
9 the consideration.

10 Q. Did you agree with the decision that
11 Phase II and III data from MMPI competitors should
12 result in the shutdown of development for ABT-518?

13 MR. LORENZINI: Objection; vague and
14 ambiguous.

15 BY MR. ZWICKER:

16 Q. In June of 2001.

17 A. You have to be very careful in your own
18 assessment whether you feel the characteristics of
19 your own compound warrant extrapolation to other
20 drugs in the same class.

21 However, if the -- the people that are
22 knowledgeable to make that decision say that that
23 is the case and the data presented from those other
24 compounds in class are not favorable, then it is --

PART 14

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 I think it's your ethical obligation to really
2 think about whether or not you feel you should
3 continue with this drug.

4 Q. Do you feel that you had a deep enough
5 understanding of the data from the competitors to
6 assess the impact of the Phase II and III trials on
7 518?

8 A. No, I didn't.

9 Q. Would you say Dr. Nabulsi did?

10 MR. LORENZINI: Objection; calls for
11 speculation.

12 BY THE WITNESS:

13 A. I don't know.

14 BY MR. ZWICKER:

15 Q. Did you have an understanding that
16 Dr. Leiden made the decision to terminate ABT-518
17 for a second time?

18 A. I have not been informed of that.

19 Q. Look again, if you would, at
20 Exhibit No. 24.

21 A. Yes.

22 Q. The very last bullet point on Section 7,
23 "Issues," "Hold was lifted from bulk drug
24 manufacturing of ABT-518."

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 think we had two or three patients in the 50
2 milligram level. I think three. So, seven in
3 total if my memory is correct.

4 Q. Seven in total?

5 A. Yeah.

6 Q. Does Abbott have clinical trials with
7 the two sites today?

8 A. Not at this moment.

9 Q. Did Abbott have any other clinical
10 trials with the two sites after 518 had been
11 terminated?

12 A. We did have with the site of Dr. Voest.
13 We did not have studies with Professor Schellens.

14 Q. Was the experience with 518 the reason
15 why Abbott did not have any further trials with
16 Dr. Schellens?

17 MR. LORENZINI: Objection.

18 BY MR. ZWICKER:

19 Q. If you know.

20 A. I do not know.

21 (WHEREUPON, a certain document was
22 marked Looman Deposition Exhibit
23 No. 26, for identification, as of
24 02-01-2007.)

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 MR. ZWICKER: Before the witness is a
2 chronology of events occurring with study M00-235.

3 BY MR. ZWICKER:

4 Q. Dr. Looman, did you -- did you write
5 this chronology?

6 A. I did.

7 Q. You did?

8 A. Yes.

9 Q. At whose direction?

10 A. My own.

11 Q. Why did you do it?

12 A. I remember at the time that this was
13 written for myself I wanted to have a clear
14 understanding what had happened with the different
15 patients because, as you can see from the
16 chronology, we had a few incidents -- incidences of
17 adverse events, which led to discussions and
18 decisions whether or not to continue with the study
19 and to escalate to a next dose.

20 And at that time I felt I wanted to have
21 a clear picture what had all -- what had happened
22 to be able to answer any questions from anybody
23 would those arise.

24 Q. And are you confident sitting here today

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 that all the information, dates and descriptions on
2 this chronology are accurate?

3 MR. LORENZINI: Objection; compound, vague and
4 ambiguous.

5 BY THE WITNESS:

6 A. I can only testify that what I wrote in
7 this chronology was based on the documents that
8 were in my possession, which would not necessarily
9 mean that they were 100 percent accurate because I
10 did not -- documents I do not have I have not
11 included in this chronology.

12 BY MR. ZWICKER:

13 Q. Okay. Are you confident -- look at the
14 listing --

15 A. Yes.

16 Q. -- for March 11, 2001. The one that
17 begins "Nabulsi calls Looman."

18 A. Yes.

19 Q. Are you confident that March 11, 2001
20 was the date that Dr. Nabulsi contacted you
21 regarding the stop of the ABT-518 project?

22 A. In my memory the conversation I had per
23 phone with Dr. Nabulsi on that Sunday afternoon in
24 my memory was the first time that I was notified

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 The time now is 1:43 p.m.

2 BY MR. ZWICKER:

3 Q. Dr. Looman, are you an oncologist by
4 training?

5 A. No, I'm not.

6 Q. What kind of -- what's your specialty?

7 A. I'm -- I have been generally trained.

8 So, no specialty.

9 MR. ZWICKER: I have no further questions.

10 MR. LORENZINI: I just have a couple
11 questions.

12 EXAMINATION

13 BY MR. LORENZINI:

14 Q. Dr. Looman, could you refer to
15 Exhibit 12, please.

16 A. Yes.

17 Q. This is an e-mail from Paige Gjelsten to
18 you, among other people, on March 13, 2001 stating,
19 "I just want to let you know that the M00-235 study
20 hold has been lifted. Professor Schellens and
21 Professor Voest have been contacted."

22 Was it your understanding on March 13,
23 2001, that someone from Abbott had contacted
24 Professor Schellens and Professor Voest to let them

PART 15

Looman, Jim (Linked) 2/1/2007 9:17:00 AM

1 know that the study hold had been lifted?

2 A. That is correct.

3 Q. And do you recall whether it was you or

4 someone else from Abbott who made the initial

5 communication to Professor Schellens and Professor

6 Voest to let them know that the hold had been

7 lifted?

8 A. I cannot remember if it -- if it was me

9 or if it was me together with Dr. Nabulsi. So, I

10 cannot -- I cannot answer that question.

11 Q. Is it possible that the first

12 communication to them of the hold being lifted was

13 a call from Dr. Nabulsi or someone else without you

14 present on the call?

15 MR. ZWICKER: Objection.

16 BY THE WITNESS:

17 A. I cannot confirm that, but it is

18 possible.

19 BY MR. ZWICKER:

20 Q. But you have no doubt that, in any

21 event, someone from Abbott contacted the two PIs on

22 March 13 as stated in this e-mail?

23 A. That is what I remember, yes.

24 MR. LORENZINI: I have no further questions.

12/04/2007 14:33 FAX 0031235544496

Abbott Medical

002

Errata Sheet

Page: 1 Of Total Pages:

I wish to make the following changes to my deposition/statement:

Page #: 9, Line #: 6
As appears in Transcript: Leidan
To: Leiden
Reason: Correct name of city

Page #: 16, Line #: 18
As appears in Transcript: leader
To: manager
Reason: this is the correct job title.

Page #: 36, Line #: 15
As appears in Transcript: Beijnen
To: Beijnen
Reason: is the correct name

Page #: 37, Line #: 17
As appears in Transcript: —
To: no others
Reason: missing from transcript

04 APR '07
DATE


DEPONENT'S SIGNATURE

12/04/2007 14:33 FAX 0031235544496

Abbott Medical

003

Errata Sheet

Page: 2 Of Total Pages

I wish to make the following changes to my deposition/statement:

Page #: 41, Line #: 7As appears in Transcript: tries toTo: nothing → leave out of textReason: 'tries to' is wrong, this will actually be donePage #: 41, Line #: 11As appears in Transcript: I do not knowTo: Abbott, datamanagement.Reason: because this is what is wasPage #: 62, Line #: 2As appears in Transcript: ToTo: leave out, start sentence with "As soon as..."Reason: otherwise sentence is not well understoodPage #: 65, Line #: 6-7As appears in Transcript: from which --To: yetReason: better reflects content of answer4/4/07
DATE
DEPONENT'S SIGNATURE

12/04/2007 14:34 FAX 0031235544496

Abbott Medical

004

Errata Sheet

Page: 3 Of Total Pages:

I wish to make the following changes to my deposition/statement:

Page #: 66, Line #: 13
As appears in Transcript: 5 o'clock
To: 5 o'clock PM
Reason: to avoid confusion over exact time of day

Page #: 110, Line #: 13
As appears in Transcript: have
To: had
Reason: interpret.

Page #: , Line #:
As appears in Transcript:
To:
Reason:

Page #: , Line #:
As appears in Transcript:
To:
Reason:

04 APR '07
DATE


DEPONENT'S SIGNATURE

Looman Deposition Exhibit 7

P's Exhibit BK

Jim,

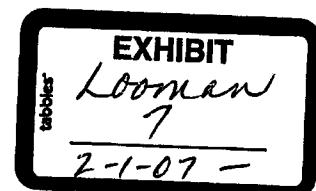
Greetings.

We had a project review with upper management this Wednesday. During this review there was a concern regarding the continuation with ABT-518 development. Although, we thought that we will be allowed to continue at this time, I and Perry have learned, 45 minutes ago, that we should stop all development activities immediately. As much as I hate to do this to you, I would like to ask you to communicate with Drs. Zonnenberg and Schellen that we are not proceeding with the trial as a result of the projects re-prioritization following the acquisition of Knoll. I will call you on your mobile phone (I do not have your home #) to discuss this further with you and check your comfort level with this very difficult task. If you prefer to call me, my home number: 847-382-3818, mobile : 847-380-5830. As you know, at AZU they are expecting a patient Monday morning, so this has to be done ASAP.

I did not have the chance to tell Todd and Diane D. this news since I was informed late in the day and they have left already. So please do not copy others until I have a chance to inform them directly.

Thanks

Azmi



Looman Deposition Exhibit 8

P's Exhibit X



Diane L
D'Amico /LAKE/PPRD/ABB
OTT

03/14/2001 12:53 PM

To Azmi A Nabulsi/LAKE/PPRD/ABBOTT@ABBOTT

cc Lori V Rountree/LAKE/PPRD/ABBOTT@ABBOTT

bcc

Subject Per Your Request

Azmi:

It is my understanding that the following chain of events led to the erroneous dosing of one patient in Abbott Study M00-235 (MMPI):

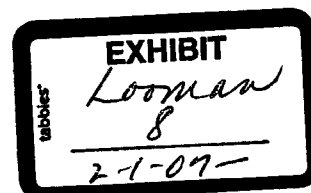
Friday, March 9 5:45 PM (CST)
Dr. Nabulsi learned that the M00-235 should be put on hold.

Sunday, March 11 10:00 AM (CST)/1700 (CET)
Dr. Nabulsi phoned Jim Looman (Associate Director, EVR Netherlands) to tell him that the M00-235 study should be put on hold. Jim Looman was instructed to contact both Dr. Schellens and Dr. Zonnenberg to notify them of the hold.

Monday, March 12 0900 AM (CET)
Jim Looman phoned Dr. Voest (Dr. Zonnenberg's superior) and alerted him to the hold on the study. The call lasted approximately 10 minutes. The patient was dosed at 0937 (CET) by Dr. Laurens Beerepoot (a sub-investigator). It appears that Dr. Voest was not able to notify Dr. Beerepoot in time. It is probably safe to assume that the patient was already at the site for Day 1 study activities at the time of the call.

Monday, March 12 0910 AM (CET)
Jim Looman phoned Dr. Schellens to notify him of the study hold. Schellens was not available to take the call. Jim then contacted Jolanda Maaskant (site QA officer) and alerted her to the study hold. The site sent home a patient who was waiting to enroll.

Diane



CONFIDENTIAL
ABBT0056817

Looman Deposition Exhibit 9

P's Exhibit S



Diane L.
D'Amico /LAKE/PPRD/ABBO
TT
03/12/2001 03:08 PM

To jhm@nid.nl

j.maaskant@telescan.nld.nl, kvi@telescan.nld.nl, Jim
Looman/HOOFDDORP/A/ABBOTT@ABBOTT, Else
Meijer/HOOFDDORP/A/ABBOTT@ABBOTT, Willy
Jansen/HOOFDDORP/ADD/ABBOTT@ABBOTT, Todd J
Janus/LAKE/PPRD/ABBOTT@ABBOTT, Paige
Gjelsten/LAKE/PPRD/ABBOTT@ABBOTT, Lori V
Rountree/LAKE/PPRD/ABBOTT@ABBOTT, Azmi A
Nabulsi/LAKE/PPRD/ABBOTT@ABBOTT, Diane C
Bronson/LAKE/PPRD/ABBOTT@ABBOTT, Robert
Hansen/LAKE/PPRD/ABBOTT@ABBOTT

cc

bcc
Subject M00-235 Update

Dear Professor Schellens,

As you know, we have been instructed to halt the M00-235 study. I assume that you know that the AZU enrolled a patient into the study today.

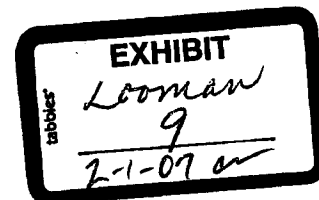
At this time, we have instructed the AZU to proceed with the M00-235 patient per the protocol until they hear from us otherwise. We hope to have further instructions by tomorrow (Tuesday, 13Mar01).

We ask that you refrain from enrolling any additional patients at your site at this time.

Thank you for your patience and understanding in this matter.

Best regards,

Diane



HIGHLY CONFIDENTIAL
ABBTO060788

Looman Deposition Exhibit 10

P's Exhibit U

MAY. 31. 2005 11:31AM

NO. 3057 P. 4

Jim Looman

13-03-2001 13:14

To: Azmi A Nabulsi/LAKE/PPRD/ABBOTT, Diane L

D'Amico/LAKE/PPRD/ABBOTT, Todd J

Janus/LAKE/PPRD/ABBOTT@ABBOTT

cc: Paige Gjelsten/LAKE/PPRD/ABBOTT, Wally

Jansen/HOOFDDORP/ADD/ABBOTT@ABBOTT, Else

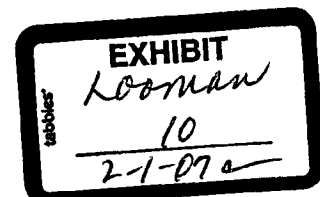
Meijer/HOOFDDORP/ADD/ABBOTT@ABBOTT

Subject: NKI study

I have just talked to the study coordinator of 518 at Prof. Schellens' site. No patients have been dosed yesterday, actually the planned patient was sent home. Prof. Schellens wants to directly speak to the US, so it is my understanding that he is going to try and phone Azmi today (Tuesday). Did you manage to talk to Prof. Voest yesterday?
speak to you later,
kind regards,
Jim

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ABBT 0033093



Looman Deposition Exhibit 12

P's Exhibit V

MAY. 31. 2005 11:31AM

NO. 3057 P. 5

Paige Gjelsten
13-03-2001 21:25

To: Jim Looman/HOOFDORP/ABBOTT@ABBOTT, Willy
Jacobs/HOOFDORP/ABBOTT@ABBOTT, Else
Majoor/HOOFDORP/ABBOTT@ABBOTT
cc: Diane L D'Amico/LAKE/PRD/ABBOTT@ABBOTT, Todd J
Jensen/LAKE/PRD/ABBOTT@ABBOTT, Azmi A
Nakula/LAKE/PRD/ABBOTT@ABBOTT, Lori V
Rountree/LAKE/PRD/ABBOTT@ABBOTT, Diane C
Barnes/LAKE/PRD/ABBOTT@ABBOTT, Robert
Hansen/LAKE/PRD/ABBOTT@ABBOTT
Subject: M00-235 Study Hold Lifted

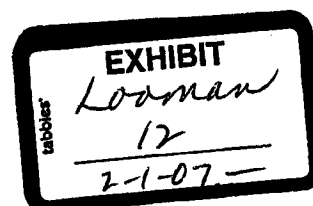
I just want to let you know that the M00-235 study hold has been lifted. Prof. Schellens and Prof. Voest have been contacted. As we gather more information, we will keep you informed.

Kind regards,

Paige

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ABBT 0033094



Looman Deposition Exhibit 18

P's Exhibit AC



Jim Looman

03/21/01 09:32 AM

To: Diane L D'Amico/LAKE/PPRD/ABBOTT, Paige
Gjelsten/LAKE/PPRD/ABBOTT@ABBOTT
cc: Else Meijer/HOOFDDORP/AI/ABBOTT@ABBOTT, Todd J
Janus/LAKE/PPRD/ABBOTT@ABBOTT, Willy
Jansen/HOOFDDORP/ADD/ABBOTT@ABBOTT, Lori V
Rountree/LAKE/PPRD/ABBOTT@ABBOTT, Azmi A
Nabulsi/LAKE/PPRD/ABBOTT
Subject: Restart 518 study

Dear Diane/Paige,

In order to re-start all activities for 518, we need the word from Azmi that he has received confirmation from both PIs that they are OK with the re-start and that they have also instructed their staffs to re-start. At the moment our site contacts are telling us that they are waiting for this official confirmation and would like to wait to do anything before that.

I have asked Else and Willy to kindly request if there are things that we could do in parallel in the meantime, but I would like to ask all of the team not to start pushing now before we have officially resolved the hold-situation. This applies to e.g. requests for getting documents, enrollment planning etc.

I am confident that we are all in agreement that the re-start should be done in the best possible way. In my view we should first get the buy-in from the PIs and then re-activate the supporting personnel. Please keep us informed on the progress of your contacts with the PI and staff.
Kind regards,

Jim
Diane L D'Amico



Diane L D'Amico

03/21/2001 12:01 AM

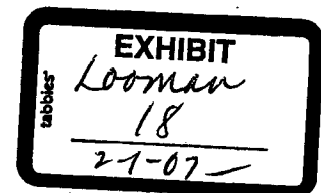
To: Else Meijer/HOOFDDORP/AI/ABBOTT@ABBOTT, Willy
Jansen/HOOFDDORP/ADD/ABBOTT@ABBOTT
cc: Jim Looman/HOOFDDORP/AI/ABBOTT@ABBOTT, Todd J
Janus/LAKE/PPRD/ABBOTT@ABBOTT, Paige
Gjelsten/LAKE/PPRD/ABBOTT@ABBOTT
Subject: M00-235 Enrollment

Dear Else and Willy,

Have you heard from either M00-235 sites what their enrollment plans are for the rest of the 25mg cohort?

Best regards,

Diane

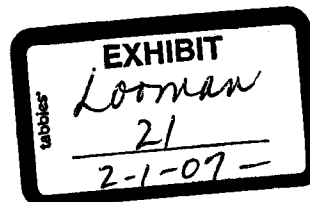


Looman Deposition Exhibit 21

P's Exhibit 51

ASCO 2001 MMPI Update

- Ten MMPI abstracts were presented
- Prinomastat, marimastat & Bay 12-9566 reported negative findings
Possible reasons
 - Under dosing due to dose limiting toxicity (joint toxicity)
 - Inappropriate tumor selection
 - Inappropriate tumor stage (late vs. early)
 - Phase II development not done for prinomastat & Bay 12-9566
- BMS 275291 did not show joint toxicity in Phase I. Phase II studies are being initiated in NSCLC & Kaposi's sarcoma



Prinomastat

- Non-small cell lung cancer
 - Combination with paclitaxel & carboplatin
 - No survival benefit
- Hormone refractory prostate cancer
 - Combination with mitoxantrone & prednisone
 - No effects on: PSA, progression free survival, overall survival
- Refractory metastatic breast cancer
 - Phase I/II single agent (n = 44)
- Grade 2 joint toxicity in above trials at all dose levels (5,10,25 mg bid)
- Studies in earlier stage tumors are still ongoing

--- Marimastat

- Small cell lung cancer
 - Following response to 1st line therapy
 - 10mg vs. placebo
 - Total 155 patients
 - No benefit on progression free survival or overall survival
- Glioblastoma
 - Post surgery & radiotherapy
 - 10mg vs. placebo
 - Total 162 patients
- High dropout rate due to joint toxicity

Bay 12-9566

- Ovarian cancer (stage III or IV)
 - 800mg bid vs. placebo
 - Study was discontinued prior to full enrollment due to lack of activity in pancreatic cancer and SCLC
 - No benefit on survival

BMS 275291

- Phase I studies
 - Healthy volunteers (n = 40 males)
 - Cancer patients (n = 44)
- No joint toxicities (possibly due to lack of sheddase activity)
- No MTD through 2400mg / day
- Phase II plan
 - Non small cell lung cancer in combination with paclitaxel & carboplatin
 - Kaposi's sarcoma
 - Dose 1200 mg / day

**ABT-518 Phase I Multiple-Dose
Study in Cancer Patients
M00-235**

- Patients enrolled to date
 - 25 mg / day 4
 - 50 mg / day $\frac{3}{7}$
- Dosing duration up to 57 days
- Patients will continue dosing until disease progression or adverse events
- No musculoskeletal effects reported to date
- Next dose is 100 mg / day

ABT-518 Development Recommendations

- Continue the ongoing Phase I study

Objectives

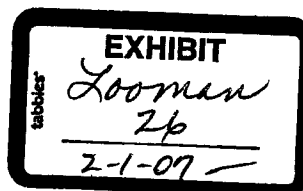
- Determine target dose required to achieve target plasma concentration of 1-3 μM
 - Assess safety following chronic administration
- Stop development if Grade 3 or 4 toxicities are attributed to doses at or below target dose
- Stop for joint toxicity
- If target dose is well tolerated, initiate a pharmacodynamic/proof of principle study with external funds (e.g., NCI-CRADA) and/or outlicense
 - Biopsy multiple melanoma, head and neck cancer, assay for gelatinase A/B activity

Looman Deposition Exhibit 26

P's Exhibit BL

Timeline of events occurring with Study M00-235 in the Netherlands

14 february 2001	Site initiation Schellens, Amsterdam
15 february 2001	Site initiation Zonnenberg, Utrecht
7 march 2001	Nisen (DVP, Oncology, Abbott US) and Nabulsi (Oncology head, Abbott US) attended Abbott senior management review: "concern regarding the continuation of ABT-518 development"
11 march 2001	Nabulsi (Oncology head, Abbott US) calls Looman (ass. Med Dir Oncology, Abbott NL) to inform about immediate stop ABT-518 project (and thus study M00-235). Janus (Med. Dir Oncology, Abbott US) and D'Amico (PM, Oncology, Abbott US)
12 march 2001	Looman calls Schellens and Zonnenberg and requests to NOT enroll any patients due to decision Abbott to stop study Zonnenberg has enrolled patient 1001; Schellens did not enrol a patient awaiting BoD approval D'Amico sends Beerepoot (sub-I, Utrecht) memo to allow continuation with pat 1001 and await further news (expected on 13 Mar 01); no new patients to be enrolled. Schellens also informed by memo (D'Amico).
13 march 2001	Abbott informs Schellens and Zonnenberg that study hold has been lifted.
23 march 2001	1001 stops study due to DP (and dies on 30 apr 01 due to cerebral mets)
26 march 2001	Schellens enrolls Pat 1002
23 april 2001	Zonnenberg enrolls pats 1003 & 1004
25 april 2001	Pat 1002: SAE (dyspnea/pleural effusion), probably not related
12-16 may 2001	ASCO: discussion by Abbott and sites: no safety issues: go to level 2 (50 mg)
18 may 2001	Memo Janus confirming escalation to level 2 (50 mg) per 21 May 2001
21 may 2001	Pat 1002 withdraws consent (due to SAE) Start patient first patient on 50 mg at NKI - 1101 JDE
22 may 2001	Start AE of 1004 (day 29 of study) - Rise of Creatinin: possibly related
25 may 2001	Hospitalization pat 1004: AE → SAE
25 may 2001	Initial SAE report pat 1004 to Abbott Safety Desk: relationship: possible related due to rising creatinin: DLT
26 may 2001	Stop medication pat 1004 to allow decrease of toxicity to within one level of baseline
30 may 2001	Follow-up SAE report; relationship: possible caused by kidney failure
30 may 2001	Zonnenberg sends letter to EC regarding pat 1002 reporting SAE: relapse pleural effusion needs to be changed into dyspnea
1 june 2001	MMPI project (ABT-518) deemed a No/Go by senior management
5 june 2001	Teleconference Abbott - Zonnenberg: relationship SAE 1004 is still possibly related, but needs to be probably not related, if enrollment of new patients at level 2 (50 mg) can continue. Schellens; 2 nd patient 1102 NKI is waiting to be included. Decision Abbott to suspend enrollment to clarify renal toxicity, based on suggestion by Zonnenberg. Patient 1004 stops study due to SAE
12 june 2001	Verbal announcement of Abbott (Nabulsi) to stop study to Schellens and Zonnenberg
14 june 2001	Teleconference with Voest to officially inform him of study termination
19 june 2001	1003 stops study due to DP
21 june 2001	Teleconference with Schellens to officially inform him of study termination After this call, an official study termination letter was sent to Schellens and Zonnenberg
22 june 2001	Receipt of registration form of proposed 2 nd patient at 50 mg by Schellens
22 june 2001	Memo Janus: relationship SAE 1004 will be changed to: probably not; Schellens to announce 2 nd patient at 50 mg; official paperwork from Zonnenberg to confirm changed relationship pending



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25 June 2001	2nd patient at 50 mg included 1102 by Schellens, however no documentation of changed relationship received from Zonnenberg. Patient should have received 25 mg due to possible DLT
26 June 2001	Visit Nabulsi to both sites to explain termination of study
6 July 2001	Conference call with Schellens asking him to not enroll new patients at 50 mg; Statement from Schellens that no more patients as of 6 Jul 01 except for pat 1101 have been enrolled at 50 mg
7 July 2001	Memo Janus to indicate that relationship has not changed, so any new patient should receive 25mg.
11 July 2001	Memo of datanurse of Zonnenberg signaling unawareness of changed relationship from probably not back to possible
12 July 2001	Renewed request to Schellens to confirm that no new patients after pat 1101 have been enrolled; Additional information received by Janus about inclusion of second patient 1102 on 25 June 01
25 July 2001	Memo from Schellens to inform Abbott that patient 1102 will continue on 50 mg, no drug related toxicities.
27 July 2001	Memo Knight (PM, Abbott Oncology US): Nabulsi agrees with proposed strategy by Schellens. Protocol deviation noted and will be reported correctly.
31 July 2001	Zonnenberg letter to Janus: Relationship SAE pat 1004 remains possibly related; recommendation Zonnenberg to add 3 more patients @ 25 mg.
10 Dec 2001	Zonnenberg sends corrective letter to EC to change description of SAE pat 1002 from "relapse pleural effusion" to "dyspnea". Content and outcome SAE have not changed.
30 Nov 01	Close out visit Schellens
11 Dec 2001	Close out visit Zonnenberg